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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/695,068 | 10/28/2003 | J. Stewart Young | MSDI-1006/PC767.01 | 5996 |
| 52196 | 7590 | 04/01/2009 | | |
| MEDTRONIC | | | EXAMINER | |
| Attn: Noreen Johnson - IP Legal Department | | | CUMBERLEDGE, JERRY L | |
| 2600 Sofamor Danek Drive | | | | |
| MEMPHIS, TN 38132 | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/695,068 | Applicant(s) YOUNG ET AL. | |
| | Examiner JERRY CUMBERLEDGE | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10-18,21 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10-18,21 and 31-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The declaration filed on 01/14/2009 under 37 CFR 1.131 has been considered but is ineffective to overcome the Jackson reference (US Pat. 6,699,248).

37 CFR 1.131(b) provides three ways in which an applicant can establish prior invention of the claimed subject matter. The showing of facts must be sufficient to show:

A) actual reduction to practice of the invention prior to the effective date of the reference

B) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the effective date of the reference date to a subsequent (actual reduction to practice); or

C) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice).

Regarding A above, the evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Jackson reference. The notebooks drawings are insufficient to establish an actual reduction to practice of the invention. In general, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. This evidence may be provided in the form of photographs, coupled with articles and/or a technical report. In re Asahi/ America Inc., 68 F.3d 442, 37 USPQd 1204, 1206 (Fed. Cir. 1995).

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Regarding B and C above, the evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Jackson reference (US Pat. 6,699,248) to either a constructive reduction to practice or an actual reduction to practice. The entire period during which diligence is required must be accounted for by either affirmative acts or acceptable excuses. Diligence requires that applicants must be specific as to dates and facts. Kendall V. Searles, 173 F. 2d 986, 993, 81 USPQ 363, 369 (CCPA 1949). There is not factual evidence supplied to establish due diligence during this entire period.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 10-16, 21, 31, 32, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 6,699,248 B2) in view of Miskew (US Pat. 4,274,401).

Jackson discloses a vertebral support apparatus said apparatus comprising: first and second spinal rods (Fig. 1, refs. 4); a solid non-hollow shaft (Fig. 3, ref. 5), wherein said shaft is solid across the entire cross-section of said shaft (Fig. 3) and includes no internal cavity (Fig. 3); a first hook (Fig. 3, ref. 14) including a first internal surface (Fig. 3) having a curved portion (Fig. 3), said first rod contacting said first internal surface

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(Fig. 3); and a second hook (Fig. 3, ref. 11) including a first end unitary and integral with the shaft at a position axially displaced from the first hook (Fig. 3), said second hook terminating at a second end spaced laterally from the shaft (Fig. 3) and comprising a second internal surface (Fig. 3) having a curved portion (Fig. 3), wherein said shaft includes a first threaded hole associated with said first hook (Fig. 3, ref. 22), and a set screw (Fig. 3, ref. 25) extends through said first threaded hole contacting said first rod (Fig. 3) and forcing said first rod against said first internal surface (Fig. 3), and wherein said shaft includes a second threaded hole (Fig. 3, near ref. 12)(Fig. 2) associated with said second hook (Fig. 3), and a set screw (Fig. 3, ref. 29) extends through said second threaded hole contacting said second rod (Fig. 3). The first end, the second end of the second hook, and the shaft define a first plane and the first hook extends laterally from the shaft along the first plane (Fig. 3). The shaft defines a substantially planar plate (Fig. 1)(Fig. 3). The apparatus comprises a first threaded aperture (Fig. 3, ref. 22) through said shaft and said curved portion of the first hook (Fig. 3). The first hook is secured to the first spinal rod and the second hook is secured to a second spinal rod (Fig. 1)(Fig. 3). The apparatus is formed as a one-piece unit (Fig. 3).

Jackson discloses a method of treating a spinal deformity, said method comprising: securing a first spinal rod and a second spinal rod to two or more vertebrae (Fig. 1); providing an apparatus according to claim 1 (above); and interconnecting the first spinal rod and the second spinal rod by securing the first spinal rod to the first hook and the second spinal rod to the second hook (Fig. 1).

Jackson discloses an interconnection apparatus for securing a pair of elongate

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members, said apparatus comprising: a solid non-hollow shaft (Fig. 3, ref. 5), wherein said shaft is solid across the entire cross-section of said shaft and includes no internal cavity (Fig. 3, ref. 5); a first hook (Fig. 3, ref. 14) including a first internal surface (Fig. 3) having a curved portion (Fig. 3) configured to at least partly encircle a first one of the pair of non-parallel, elongate members (Fig. 1); and a second hook (Fig. 3, ref. 20) including a first end unitary and integral with the shaft at a position axially displaced from the first hook (Fig. 1, end of ref. 11), said second hook terminating at a second end (Fig. 3) spaced laterally from the shaft (Fig. 3) and comprising a second internal surface (Fig. 3), and said shaft, first hook and second hook being a one-piece unit (Fig. 2). The apparatus comprises a first spinal rod secured to the first rod connector (Fig. 1, ref. 4) and a second spinal rod secured to the second rod connector (Fig. 1, ref. 4). The axial distance between said first hook and said second hook is permanent and non-adjustable (Fig. 3).

Jackson discloses a vertebral support apparatus comprising: first and second elongated support rods (Fig. 1, refs. 4); a one-piece connector engaging both of said rods (Fig. 3, ref. 5), said connector having a solid non-hollow shaft (Fig. 3, ref. 5), wherein said shaft is solid across the entire cross-section of said shaft and includes no internal cavity (Fig. 3, ref. 5), said connector further having a first hook portion (Fig. 3, ref. 14) with a blade (*i.e.* tip, as discussed above, in the objection) (Fig. 3) laterally spaced from said shaft and pointing generally along the direction of said shaft first internal surface having a curved portion configured to at least partly encircle a first one of elongate support rods (Fig. 1)(Fig. 3), said connector farther having a second hook

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portion (Fig. 3, ref. 11) laterally spaced from said shaft and pointing generally along the direction of said shaft and a first end attached to said shaft at a position displaced along said shaft from said first hook (Fig. 3), said second hook (Fig. 3, ref. 11) terminating at a second end spaced laterally from said shaft (Fig. 3, end of ref. 11) and comprising a second internal surface (Fig. 3) having a curved portion (Fig. 3), wherein said first rod is locked in contact with said first internal surface of said first hook, and said second rod is locked in contact with said saddle, said first rod and said second rod being non-parallel.

Jackson discloses the claimed invention except for the curved portion including a ridge extending along said curved portion in a direction from the first end to the second end, wherein said second rod contacts said ridge; the second internal surface curves both in a first direction from the shaft to the second end and in a second direction oblique to the first direction, wherein said curves in said first and second directions are overlapping and intersecting; the internal surface curves in a second direction substantially orthogonal to the first direction; the internal surface curves in a second direction at an acute angle to the first direction; the internal surface curves in a second direction at an obtuse angle to the first direction; and a saddle extending along said curved portion in a direction from said first end to said second end. Jackson does disclose a set screw that presses a thread into the rod in order to provide stability to the construct (column 2, lines 66-67)(column 3, lines 1-10).

Miskew discloses a spinal apparatus (Fig. 7) that comprises hooks (Fig. 5, ref. 74) that comprise ridges (or saddles) (Fig. 5, ref. 78) that extend along the curved portion of the hooks and produce curves in multiple directions. The ridges being used to

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press into bone (Fig. 5) in order to provide stability to the construct (column 6, lines 29-38).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the thread mechanism disclosed by Jackson with the ridge mechanism disclosed by Miskew, in order to achieve the predictable result of providing stability to the construct.

With regard to the acute and obtuse angles of the ridge, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the ridge as being obtuse or acute, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 6,699,248 B2) in view of Miskew (US Pat. 4,274,401) in view of Lombardo (US Pat. 6,238,396 B1).

Jackson discloses the claimed invention except for the shaft having a round or oval cross-sectional profile and the shaft being curved. Jackson does disclose a shaft that is used to connect two hooks (Fig. 3, ref. 5)

Lombardo discloses a spinal device that comprises hooks (Fig. 12A) that comprises a shaft that has a round profile (Fig. 12A, ref. 73) that can be either straight or curved (Fig. 12A)(Fig. 12B)(Fig. 12C). The shaft is used to connect two hooks (Fig. 12A)(Fig. 12B)(Fig. 12C).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the shaft of Jackson with any of the shafts of Lombardo in order to achieve the predictable result of connecting two hooks.

Claims 7, 8, 17, 18, 33, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 6,699,248 B2) in view of Miskew (US Pat. 4,274,401) in view of Jackson (US Pat. 5,980,523).

Jackson '248 discloses the claimed invention except for the first spinal rod and the second spinal rod are positioned to lie non-parallel to each other. The first spinal rod and the second spinal rod are positioned to not lie in the same plane.

Jackson '523 discloses a spinal stabilization system that comprises rods that are positioned non-parallel and non-planar to one another (Fig. 25). This allows for greater adjustability during surgical procedures (column 5, lines 28-47).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Jackson '248 with the spinal rods being positioned to lie non-parallel and non-planar to one another, in order to allow for greater adjustability during surgical procedures (column 5, lines 28-47).

Response to Arguments

Applicant's arguments directed to the declaration filed 01/14/2009 have been fully considered but they are not persuasive, as described above in the "Response to Amendments" section.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733